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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,025	10/10/2001	Geert Maertens	2752-56	7266

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/973,025	MAERTENS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *06/17/2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☒ Newly proposed or amended claim(s) *114* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: *105,106,113-115 and 118*.

   Claim(s) rejected: *100-104, 107-112, 116-117*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *PTO Form 892*

Bao Qun Li

Continuation of 5. does NOT place the application in condition for allowance because: the argument has been fuly considered; however, is not persuasive to overcome the outstanding 102 rejection.

Advisory Action

The response to the final action filed on October 31 under 37 CFR 1.116 has been entered. However, the amendment of the claim has been considered. However, it has not been entered. Because the amendment does not place the rest application in the condition for allowance.

For purpose of appeal, the status of the claims is as follows:

Allowed claims: None.

Rejected claim (s): 100-104, 107-112, and 116-117.

Claim(s) objected to: NONE.

Claims 114-115 are free of art rejection. However, they are not in the condition for allowance because it depends on the rejected claim 100. The examiner apologizes that there is a typographic error in the last office action in that claims free of art should be claims 114 and 115 instead of claims 112 and 115.

Claim 105 is free of art rejection. However, claim is not in the condition for allowance because the scope of the claim 115 reads more broad then the independent claim 100.

Claims 106 and 118 are free of art rejection. However, it is not in the condition for allowance because they depend on the rejected claim 100.

Claim 113 is not in the condition for allowance because it depends on the rejected claim 100.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 100-104, 107-112 and 116-117 are still rejected under 35 U.S.C. 102(a) as being anticipated by Mehta et al. (Patent No. 5,308,750A) on the same ground as stated in the previous Office Action.

3. Applicants traverse the rejection and submitted that according to the record of Mehta et al. in the application Serial No. 07/610,180, now patent No. 610,180 that Mehta et al. did not

produce a monoclonal antibody with that disclosed peptide sequences. Therefore, Section 102 rejection of claims 100-104, 107-1 12 and 116-1 17 over Mehta should be withdrawn.

4. Applicants' argument has been respectfully considered; however, it is not found persuasive because the only independent claim 100 read on any antibody that binds to at least one region within a domain spanning amino acids 416-650, or 655-809 of the hepatitis C virus polypeptide, which leaves the scope open to any monoclonal antibody that binds to a region that may be as short as 5 to 10 amino acid in the two claimed domains.

5. It is well known in the art that a monoclonal antibody is able to bind as short as 5 to 20 amino acids of an immunogenic epitop in an immunogenic polypeptide, and sometime, a single amino acid residue contributes the majority of the binding interaction between the antibody and antigen. For exemple, Petit et al. (J. Biol. Chemistr. 2003, Vol. 278, pp. 45, pp. 44385-44392) teach that the monoclonal antibody D32.10 binds to several epitopes from 8 to 15 amino acid residues in the region of amino acid residues 607-627 of HCV E2 (See Table VI on page 44389) and E1 (See Table I and Fig. 2 on page 44388). They also teach that in the sequences of E1 (a.a. 292-306), E2 (a.a 480-494), and E2 (a.a 608-622), the cystein residues located at Cys306, Cys494, and Cys620 are the only amino acid residues that react strongly with the antibody D32.10 (See the 1st column of page 44389, especially lines 8-30), suggesting that one single monoclonal antibody can bind to several epitopes of a polypeptide.

6. Therefore, the monoclonal antibody e.g. H13C113 or H23C163 disclosed by Mehta et al. binds to the epitops situated in the region of amino acids residues 649-655, some of these epitops are coexistent in the regions 416-650 and 655-809 of the rejected claim 100. Therefore, the antibody disclosed by Mehta et al. still anticipates the claimed monoclonal antibody. Thus, the rejection is maintained.

7. Applicants are reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. **See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) [PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical.] While "indirect comparisons, based on established scientific principles, can validly be applied to distinguish a claimed chemical process or product from that disclosed**

in the prior art," In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 432 (CCPA 1977), the comparisons must be scientifically valid. It is Patent owner's burden under the circumstances presented herein was described in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows: Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
Art Unit 1648
10/07/2004

James C. Housel
JAMES HOUSEL 10/18/04
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